UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

June 27, 2013

MEMORANDUM

Subject: Efficacy Review for Super-Chlor, EPA Reg. No. 69687-1; DB Barcode: D412068.

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Applicant: Medtrol, Inc.
7157 North Austin Avenue
Niles, IL 60714

Formulation from the Label:

Active Ingredient(s)	% by wt.
Sodium hypochlorite	0.65 %
Other ingredients*	99.35 %
Total	100.00 %

* Other Ingredients do not include the weight of towelette.

I. BACKGROUND

The product, Super-Chlor (EPA Reg. No. 69687-1), is an EPA-approved disinfectant (bactericide, fungicide, and virucide) for use on hard, non-porous surfaces in institutional, and hospital or medical environments. The applicant requested, to amend the registration of this product to add claims for effectiveness as a disinfectant against spores of *Clostridium difficile*. Previously submitted efficacy studies (MRID nos. 489534-01 through 489534-05) were reviewed and registrant was asked to submit a confirmatory efficacy data, using ASTM E 2197 with expressed liquid (at LCL), on one lot of the towelette product Super-Chlor. Study was conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121.

This data package contained a letter from the applicant to EPA (dated May 30, 2013), one study (MRID 490873-01), Statements of No Data Confidentiality Claims for the study, and the proposed label (Version 3, dated 05-30-2013).

II. USE DIRECTIONS

The product is designed for disinfecting hard, non-porous surfaces, including: blood glucose meters, carts, cellular phones, counters, examination tables, headsets, patient care equipment, sinks, stethoscopes, telephones, and toilet seats. The proposed label does not identify the types of surfaces on which the product may be used (e.g., stainless steel, glass). Directions on the proposed label provide the following information regarding use of the product as a disinfectant: Thoroughly clean gross filth and heavy soil from surfaces prior to disinfection. Apply towelette and wipe desired surface. Allow treated surfaces to remain thoroughly wet for 5 minutes (3 minutes against *Clostridium difficile* spores). Allow surface to air dry.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Sporicidal Disinfectant against *Clostridium difficile*: The Agency has established interim guidance for the efficacy evaluation of antimicrobial products (e.g., dilutable products, ready-to-use products, spray products, towelettes) that are labeled for use to treat hard, non-porous surfaces in healthcare settings contaminated with spores of *Clostridium difficile*. The effectiveness of such a product must be substantiated by data derived from one of the following two test methods: AOAC Method 2008.05: Quantitative Three Step Method (Efficacy of Liquid Sporicides Against Spores of *Bacillus subtilis* on a Hard Nonporous Surface); and ASTM E 2197-02: Standard Quantitative Carrier Test Method to Evaluate the Bactericidal, Fungicidal, Mycobactericidal, and Sporicidal Potencies of Liquid Chemical Germicides. Modifications to each test method will be necessary to specifically accommodate spores of *Clostridium difficile*. Because *Clostridium difficile* is an obligate anaerobe, testing should ensure adequate incubation conditions for the recovery of viable spores. The toxigenic strains, ATCC 43598, of *Clostridium difficile* must be used for testing. Results must show a minimum 6 log reduction of viable spores in 10 minutes or less. Control carrier counts must be greater than 10^6 spores/carrier.

Supplemental Claims: An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum.

IV. BRIEF DESCRIPTION OF THE DATA

1. MRID 490873-01 "Standard Quantitative Disk Carrier Test Method" Test Organism: *Clostridium difficile* - spore form (ATCC 43598) for Super-Chlor, by Jill Rhume. Study conducted at ATS Labs. Study completion date – March 15, 2013. Project Identification Number A14726.

The study was conducted against *Clostridium difficile* - spore form (ATCC 43598). One lot of the product Super-Chlor, Lot B25EXP0114, was tested using ATS Laboratory Protocol No. MRL01022613.QDCT (copy provided). The product was received ready-to-use, as a pre-saturated towelette. The fluid present in the disinfectant wipes was expressed and collected in sterile containers. The product was not tested with a 3-part soil load incorporated into the test inoculum by adding 25 µl of 5% bovine serum albumin, 35 µl of 5% yeast extract and 100 µl of 0.4% mucin to 340 µl of the spore suspension. Ten (10) brushed sterile stainless steel disk carriers (1 cm diameter) were inoculated with 10 µL of the spore suspension. The carriers were dried in a vacuum desiccator containing anhydrous calcium chloride for 4.5 hours under ambient conditions. Each carrier was transferred, inoculated side up, to a sterile 15 mL vial, to which 50 µL of the expressed liquid was added. The carriers remained exposed to the expressed liquid for 3 minutes at room temperature (21°C) and 19% relative humidity. Following exposure, 10 mL of neutralizer was added to each vial to neutralize. Carriers were scraped with sterile loop to elute any visible inoculum. The vials were vortex mixed for 45-60 seconds. Within 30 minutes, the entire liquid volume of each vial was individually filtered through a pre-wetted filter using a vacuum pump. Each vial was rinsed four times with 10 mL of sterile saline, and the rinsate was filtered. Each membrane filter was placed, up side up, on the surface of a Petri plate containing Brain Heart Infusion agar modified for *Clostridium* species. Each Petri plate containing a membrane filter was incubated for 48±4 hours at 35-37°C under anaerobic conditions. Following incubation, final plate counts were made. Controls included those for carrier count, purity, sterility, verification of neutralizer efficacy (the single product lot), and acid resistance at 5, 10, and 20 minutes. The product lot B25EXP0114 was reported to contain 6216 ppm NaOCl before testing.

Note: For the HCl resistance control assay, 10 µl of the spore suspension were transferred to micro-centrifuge tubes containing 990 µl of 2.5N HCl at room temperature and 990 µl of sterile deionized water for control. Tubes were incubated for either, 5 minutes, 10 minutes, or 20 minutes prior to transferring 0.1 ml of suspension to 900 µl of Phosphate Buffer Dilution Water to neutralize. Each diluted tube was serially diluted, plated, incubated and colonies were counted. The acceptance criterion is ≤2 $\log_{10}$ reduction following 10 minutes of exposure compared to the control.

V. RESULTS

MRID Number	HCL Resistance Control CFU/ml ($\log_{10}$) Log reduction/pass or fail				Results for Lot B25EXP0114 CFU/ml ($\log_{10}$) Log reduction	Carrier Population (CFU/carrier)
	Minutes of exposure			Control		
	5	10	20		3-Minutes Exposure Period	
490873-01	2.52×10^5 (5.40)	9.4×10^4 (4.97)	3.5×10^4 (4.54)	9.2×10^5 (5.96)	<1 (<0.00)	3.89×10^6
	0.56/NA	0.99/Pass	1.42/Pass	NA/NA	>99.9999	

VI. CONCLUSION

1. The submitted efficacy data (MRID 490873-01) in conjunction with previously submitted data (MRID nos. 489534-01 through 489534-05) **support** the use of Super-Chlor as a disinfectant with sporicidal activity against *Clostridium difficile* spores on hard, non-porous surfaces for a contact time of 3 minutes at 20.0°C.

VI. LABEL

1. The proposed label claims that the product, Super-Chlor, is an effective disinfectant with sporicidal activity against *Clostridium difficile*-spore form, on hard, non-porous surfaces for a contact time of 3 minutes at 20.0°C, **are supported** by the applicant's data.